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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/200,657	11/25/1998	MICH B. HEIN	TSRI-184.2CO	9640

7590 10/27/2003

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SAN DIEGO, CA 92138-0278

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

42

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/200,657

Applicant(s)

HEIN ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on May 30, 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 79,81-85,87-90 and 93-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 79,81-85,87-90 and 93-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed April 2, 2003, and the supplemental response filed May 30, 2003, have been entered.

Claims 1-78, 80, 86, 91-92 and 96-99 are cancelled.

Claims 79 and 81-83 are presently amended.

Claims 79, 81-85, 87-90 and 93-95 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Inventorship***

Applicant inquires as to the status of a request to correct inventorship under 37 CFR 1.48(b) filed March 4, 2002 along with the Request for Continued Examination (reply pages 6-7).

Receipt is acknowledged of the request to correct inventorship under 37 CFR 1.48(b), filed March 4, 2002 with the Request for Continued Examination. The inventorship in this nonprovisional application has been changed by the deletion of Julian Ma.

### ***Double Patenting***

Claims 79, 81-85, 87-90 and 93-95 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-66

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of copending Application No. 09/512,736, for the reasons of record set forth in the office action mailed July 5, 2001.

The Office acknowledges Applicant's request that the terminal disclaimer filed with the previous amendment be entered in the case in order to overcome the rejection (reply March 4, 2002, page 9).

***Claim Rejections - 35 USC § 112***

Claim 83, and claims 79, 81-82, 84-85, 87-90 and 93-95 dependent thereon, remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "derived", for the reasons of record set forth in the office action mailed January 1, 2003. The rejection of dependent claims 79 and 81-82 was inadvertently omitted from the rejection set forth in the office action mailed January 1, 2003, but it is clear from the record that claims 79 and 81-82 would also be indefinite as a consequence of their incorporation of the term "derived". Any inconvenience to Applicant is regretted.

Applicant's arguments filed April 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that "derived" is not indefinite because the skilled artisan would know how to chose which portion of the heavy chain would be need under a particular set of circumstances. Applicant additionally points out that the claims require that the heavy chain be capable of assembly with a light chain antibody to produce an antigen specific immunoglobulin in a plant cell, and that one skilled in the art would know what is needed and what could be eliminated or modified to meet this functional requirement. Applicant additionally points to the

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fact that the engineering of antibodies is known in the art, and points in particular page 3 of the specification and US Patent No. 4,816,567 as being illustrative of this fact. Applicant argues that derived would thus be understood by one skilled in the art when read in light of the specification (reply pages 7-9).

The Office maintains that the term “derived” as it is used in the rejected claims is indefinite. Neither the general knowledge of one skilled in the art regarding antibody engineering nor the claim requirement that the heavy chain be capable of assembly with a light chain antibody to produce an antigen specific immunoglobulin in a plant cell clarifies what part of the heavy chain would be derived from an antigen-specific immunoglobulin and what part would be retained by an antigen-specific immunoglobulin with respect to the heavy chain of the instant invention, as it is unclear what components, if any, in addition to those required to meet the functional requirement, a “derived” heavy chain would derive from the antigen specific immunoglobulin.

Claim 84, and claims 85-87 dependent thereon, remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “is a multimer”, for the reasons of record set forth in the office action mailed January 1, 2003.

Applicant's arguments filed April 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that it is well known that a single polypeptide may associate with another polypeptide to form a multimer, and points out that the claims require nucleotide

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sequence encoding an immunoglobulin single polypeptide product but do not limit association of the product once produced (reply page 9).

The Office does not dispute that it is well known that a single polypeptide may associate with another polypeptide to form a multimer, but maintains that the rejected claims are indefinite. The recitation of “an immunoglobulin single polypeptide product” implies a product that is a single polypeptide, rather than a product that comprises a single type of polypeptide. Additionally, the rejected claim does not recite that the single polypeptides associate to form a multimer. Furthermore, the specification does not explicitly define “an immunoglobulin single polypeptide product”, and the single polypeptide immunoglobulins exemplified appear to be monomeric.

Presently amended claim 83, and claims 79, 81-82, 84-85, 87-90 and 93-95 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “wherein said plant cells do not contain nucleic acid encoding said light chain”. It is unclear whether the plant cells do not contain any nucleic acid encoding a light chain polypeptide, or whether the plant cells do not contain only the nucleic acid encoding the specific light chain from the particular antigen-specific immunoglobulin that the heavy chain is derived from.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

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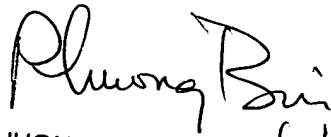
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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

October 6, 2003

  
PHUONG T. BUI  
PRIMARY EXAMINER 10/6/03